

Food and Drug Administration, HHS

§ 870.4390

**§ 870.4310 Cardiopulmonary bypass coronary pressure gauge.**

(a) *Identification.* A cardiopulmonary bypass coronary pressure gauge is a device used in cardiopulmonary bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

(b) *Classification.* Class II (performance standards).

**§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.**

(a) *Identification.* A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

**§ 870.4330 Cardiopulmonary bypass on-line blood gas monitor.**

(a) *Identification.* A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

(b) *Classification.* Class II (performance standards).

**§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.**

(a) *Identification.* A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

(b) *Classification.* Class II (performance standards).

**§ 870.4350 Cardiopulmonary bypass oxygenator.**

(a) *Identification.* A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

**§ 870.4360 Nonroller-type cardiopulmonary bypass blood pump.**

(a) *Identification.* A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

**§ 870.4370 Roller-type cardiopulmonary bypass blood pump.**

(a) *Identification.* A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class II (performance standards).

**§ 870.4380 Cardiopulmonary bypass pump speed control.**

(a) *Identification.* A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

(b) *Classification.* Class II (performance standards).

**§ 870.4390 Cardiopulmonary bypass pump tubing.**

(a) *Identification.* A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood

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to flow through the cardiopulmonary bypass circuit.

(b) *Classification*. Class II (performance standards).

### § 870.4400 Cardiopulmonary bypass blood reservoir.

(a) *Identification*. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.

(b) *Classification*. Class II (performance standards), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter.

### § 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) *Identification*. A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

(b) *Classification*. Class II (performance standards).

### § 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) *Identification*. A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

(b) *Classification*. Class II (performance standards).

### § 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) *Identification*. A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

(b) *Classification*. Class II (performance standards).

### § 870.4450 Vascular clamp.

(a) *Identification*. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

(b) *Classification*. Class II (performance standards).

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### § 870.4475 Surgical vessel dilator.

(a) *Identification*. A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) *Classification*. Class II (performance standards).

### § 870.4500 Cardiovascular surgical instruments.

(a) *Identification*. Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

### § 870.4875 Intraluminal artery stripper.

(a) *Identification*. An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)

(b) *Classification*. Class II (performance standards).

### § 870.4885 External vein stripper.

(a) *Identification*. An external vein stripper is an extravascular device used to remove a section of a vein.

(b) *Classification*. Class II (performance standards).

## Subpart F—Cardiovascular Therapeutic Devices

### § 870.5050 Patient care suction apparatus.

(a) *Identification*. A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) *Classification*. Class II (performance standards).

### § 870.5150 Embolectomy catheter.

(a) *Identification*. An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli,